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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/207,188 12/08/98 BLAKE

M 2016-4005US1

EXAMINER

HM22/0212

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NEW YORK NY 10154

DEVT. S
ART UNIT

PAPER NUMBER

1645
DATE MAILED:

02/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/207,188

Applicant(s)

Blake et al.

Examiner

S. Devi, Ph.D.

Group Art Unit

1645



☒ Responsive to communication(s) filed on 11/17/2000.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 61-79 ~~is~~are pending in the application.

Of the above, claim(s) 73-79 ~~is~~are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 61-72 ~~is~~are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendment filed 11/17/00 (paper no. 11), which amendment has been entered.

Status of Claims

- 2) Claims 61-79 are pending in this application.
Claims 73-79 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03.
Claims 61-72 are under examination.

Prior Citation of Title 35 Sections

- 3) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 5) The objection to the specification made in paragraph 9(a) of the Office Action mailed 07/14/00 (paper no. 7) is withdrawn in light of Applicants' amendment to the specification.
- 6) The objection to the description for Figure 4 made in paragraph 9(b) of the Office Action mailed 07/14/00 (paper no. 7) is withdrawn in light of Applicants' amendment to the specification.
- 7) The objection to the specification made in paragraph 9(c) of the Office Action mailed 07/14/00 (paper no. 7) is withdrawn in light of Applicants' amendment to the specification.
- 8) The objection to the specification made in paragraph 9(d) of the Office Action mailed 07/14/00 (paper no. 7) is withdrawn in light of Applicants' clarification.
- 9) The objection to claim 61 made in in paragraph 16(a) of the Office Action mailed 07/14/00 (paper no. 7) is withdrawn in light of Applicants' amendment to the claim.
- 10) The objection to claim 70 made in in paragraph 16(b) of the Office Action mailed

07/14/00 (paper no. 7) is withdrawn partly in light of the Applicants' explanation.

Applicants state that the term "QS21" is definite. The Office would like to clarify that claim 70 was not rejected as being "indefinite", instead the claim was objected to.

Objection(s) Maintained

11) The objection to the description for Figure 1 made in paragraph 9(b) of the Office Action mailed 07/14/00 (paper no. 7) is maintained for reasons set forth therein. Applicants have not addressed the issue.

Rejection(s) Withdrawn

12) The rejection of claim 61 made in paragraph 11(a) of the Office Action mailed 07/14/00 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn.

13) The rejection of claim 62 made in paragraph 11(b) of the Office Action mailed 07/14/00 (paper no. 7) under 35 U.S.C 35 § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

14) The rejection of claim 63 made in paragraph 11(c) of the Office Action mailed 07/14/00 (paper no. 7) under 35 U.S.C 35 § 112, second paragraph, as being indefinite, is withdrawn upon further consideration.

15) The rejection of claim 67 made in paragraph 11(d) of the Office Action mailed 07/14/00 (paper no. 7) under 35 U.S.C 35 § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

16) The rejection of claim 68 made in paragraph 11(e) of the Office Action mailed 07/14/00 (paper no. 7) under 35 U.S.C 35 § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

Rejection(s) Maintained

17) The rejection of claims 61-63, 68 and 69 made in paragraph 13 of the Office Action mailed 07/14/00 (paper no. 7) under 35 U.S.C § 102(b) as being anticipated by Reimer *et al.* (*Carbohydr. Res.* 232: 131-142, 1992), is maintained for reasons set forth therein and herebelow.

Applicants argue that Reimer's method does not use a group A streptococcal polysaccharide comprising about 3 to about 30 repeat units. The Applicants' argument has been

carefully considered, but is not persuasive.

Instant claims are directed to a method of immunizing a mammal comprising administering an immunogenic amount of the recited polysaccharide of formula (I) covalently linked to a protein, wherein n in the formula encompasses a number of "about 3". Absent a description in the specification, as originally filed, for what is encompassed in the recitation "about 3", the group A streptococcal polysaccharide contained in the Reimer's conjugate having more than one trisaccharide unit qualifies as the instantly recited polysaccharide wherein n is "about" 3. In the instant rejection, "about 3" is interpreted as being equivalent to 3 ± 2 or 3 ± 1.5 and therefore Reimer's method anticipates the instant invention.

The immunization method of Reimer *et al.* is described in paragraph 13 of the Office Action mailed 07/14/00. Reimer's method of immunizing a mammal comprising administering a group A streptococcal polysaccharide conjugated to a protein anticipates the instantly claimed method, because Reimer's conjugate comprises a group A polysaccharide of the recited formula wherein n is equivalent to one or more than one trisaccharide unit (i.e., "about" 3). For example, see the conjugates 1a, 2a and 3a as depicted on page 136, below Table 1. The prior art conjugate(s) is contained in PBS and Freund's complete adjuvant and the conjugate is used for immunization of rabbits (see page 133, first full paragraph). The rejection stands in the absence of an explanation as to whether 1 or 1.5 repeat unit (n) is encompassed in the recitation of "about" 3.

18) The rejection of claims 61-72 made in paragraph 15 of the Office Action mailed 07/14/00 (paper no. 7) 35 U.S.C § 103(a) as being unpatentable over Reimer *et al.* (*Carbohydr. Res.* 232: 131-142, 1992) in view of Jennings *et al.* (US 4,356,170) and Barnes *et al.* (WO 87/06590), is maintained for reasons set forth therein and those set forth below.

Applicants contend that to establish a *prima facie* case of obviousness, there must be some suggestion or motivation either in the references or "in the knowledge generally available to one of ordinary skill in the art to modify the reference", a reasonable expectation of success or reference(s) teaching or suggesting all the claim limitations. Applicants allege that the Office has not provided evidence of motivation or suggestion to modify the references and has failed to show a reasonable expectation of success. Applicants further point to the McCarty Declaration, filed 12/08/99, stating that the art did not consider the group A streptococcal polysaccharide to be

relevant in connection with "eliciting a protective immunogenic response". Applicants further point to the issuance of the US patent 5,866,135 directed to the product used in the instant invention.

The Applicants' arguments have been carefully considered, but are not persuasive. The Office agrees with the Applicants that there must be motivation in the references or "in the knowledge generally available to one of ordinary skill in the art" to modify the reference to establish a *prima facie* case of obviousness. In the instant rejection, the motivation comes from the knowledge generally known to those skilled in the art of conjugate vaccines that a microbial protein, such as tetanus toxoid or diphtheria toxoid, would serve as a clinically more useful carrier protein in a conjugate compared to BSA. One would have had a reasonable expectation of success in substituting Reimer's BSA with Jennings' medically useful carrier protein, such as diphtheria toxoid or tetanus toxoid, to produce the instant invention since such a substitution has been conventionally practiced in the art of conjugate vaccines with success. Absent a showing that substituting Reimer's BSA with Jennings' tetanus toxoid or diphtheria toxoid would result in a streptococcal polysaccharide-protein conjugate that is non-immunogenic or not optimally immunogenic, the rejection stands. As set forth in paragraph 15 of the Office Action mailed 07/14/00 (paper no. 7), the motivation to substitute Reimer's Freund's complete adjuvant with Jennings' non-toxic adjuvant, such as, aluminum hydroxide or aluminum phosphate, comes from the teachings of Barnes *et al.* who explicitly teach that Freund's complete adjuvant is unsatisfactory for human use since it causes large undesired lesions at the site of injection.

With regard to Applicants' remarks on McCarty statement on the protective immunogenic response, Applicants are reminded that instant methods are drawn to a "method of immunizing a mammal" with the recited conjugate, which is clearly taught by Reimer *et al.* With regard to Applicants' remarks on the issuance of the US patent 5,866,135, it should be noted that the prosecution of one application does not have to duplicate that of a previous application. For example, just because the previous prosecution resulted in the allowance of claim 12 which contained the redundant recitation "is is", it does not mean that a claim with a similar incorrect claim language should be allowed during the current prosecution.

Double Patenting Rejection(s)

19) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

20) Claims 61-72 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 26-33 of the U.S. Patent 5,866,135. Although the conflicting claims are not identical, they are not patentably distinct from each other, because the instantly claimed method of immunization is encompassed in the scope of claims 26-33 of the U.S. Patent 5,866,135.

Furthermore, there is no apparent reason why Applicants were prevented from presenting claims corresponding to those of the instant application during the prosecution of the parent application which matured into US Patent 5,866,135. See *In re Sachneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Remarks

21) Claims 61-72 stand rejected.

22) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone

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number is (703) 308-4242, which receives papers seven days a week and 24 hours a day.

23) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD
S. Devi, Ph.D.
Patent Examiner
February 2001